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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/557,423	04/21/2000	Boris P. Belotserkovskii	A-68112-1/RFT/RMS/DSS	6773

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01/28/2004

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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/557,423

Applicant(s)

BELOTSERKOVSKII ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 114-142 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 116-118 and 120 is/are allowed.
- 6) ☒ Claim(s) 114, 119, 121-137, 139, 140 and 142 is/are rejected.
- 7) ☒ Claim(s) 115, 138 and 141 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 3, 2003 has been entered.

Claims 1-113 were cancelled in the application, and new claims 114-142 were added. Claims 114-142 are pending and ready for examination in the instant application.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 119, 121-127 and 129-135 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 119 introduces the limitation "with the proviso that said locking complex is not an internal homology clamp." There is no support in the specification for this

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negative limitation. Applicant indicates in their arguments that page 21, lines 34-40 provides support for this amendment. However, an examination of the contents of the citation does not indicate any support for the negative limitation. Rather, the citation indicates the use of an internal homology clamp, as opposed to not using an internal homology clamp. Furthermore, as defined by the same citation, an internal homology clamp is a simple form of anchoring sequence. Thus, because one of skill in the art has no reasonable manner by which to surmise which homology clamps are “simple” or “not simple,” the skilled artisan cannot determine what constitutes “not using an internal homology clamp” from the original disclosure (see also the rejection under 35 USC § 112, second paragraph). As a result, this limitation represents new matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 119, 121-127 and 129-135 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 119 introduces the limitation “with the proviso that said locking complex is not an internal homology clamp.” Applicant defines an internal homology clamp as a simple form of anchoring/locking sequence. This limitation is indefinite because there is no definition of what constitutes a “simple” or “complex” anchoring/locking sequence; therefore the metes and bounds of what locking sequences can or cannot be used is unclear.

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Claim 35 recites the limitation "the cell of claim 122" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 122 is directed to a composition of nucleic acids, not a cell. It would be remedial to indicate that the dependency of claim 135 is properly to claim 133.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 114, 121-127, 129-137, 139, 140 and 142 are rejected under 35 U.S.C. 102(e) as being anticipated by Pati *et al.* (as cited in the previous Office Actions; henceforth Pati; see the entire document). **This rejection is maintained for essentially the same reasons set forth in the previous rejection.**

For purposes of clarity, and because of the cancellation of the previous claims in favor of the new claims, the rejection is reiterated below in terms of the new claims.

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Pati teaches a composition comprising a double D-loop comprising a target nucleic acid, and a first and second nucleic acid sequence, each of which has two flanking regions with homology to the target nucleic acid, wherein said flanking regions flank a center region which is capable of forming an internal homology clamp (see for example Figure 13B and the corresponding description thereof). By Applicant's own definition (see for example page 21, lines 34-40 of the instant specification), an internal homology clamp represents a locking sequence. Therefore, Pati teaches all of the structural features of the instantly claimed invention. Regarding the provision that the locking complex confers upon the double D-loop a half-life that is increased at least 5-fold, Pati must inherently teach this functional property because Pati teaches all of the structural limitations of the invention. Absent a clear indication of a structural feature that is not present in the teachings of Pati that results in the allegedly non-anticipated functional feature of the instant claims, there is no reason to believe that Pati does not inherently teach this property.

Pati additionally teaches coating the double D-loop structure with a recombinase or recombinase complex, specifically either *E. coli* RecA or Rad51 (see for example column 24, lines 22-23 and 30-35). Importantly, the internal homology clamp of Pati is comprised of DNA. Additionally, Pati anticipates modifying at least one of the single stranded nucleic acids with chemical substituents such as cross-linking agents, topoisomerases (i.e., a protein), etc. (see for example column 27, lines 40-65). Finally, Pati also teaches host cells comprising these compositions that may be either prokaryotic or eukaryotic in nature (see for example column 29, lines 5-27). As a result, Pati anticipates each and every element that is set forth in the rejected claims.

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The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Response to Arguments Concerning Claim Rejections - 35 USC § 102

Applicant's arguments filed December 3, 2003 have been fully considered but they are not persuasive. Applicant's arguments consist of the following points:

1. The rejection under Pati is rendered moot by the cancellation of the previous claims.
2. Pati does not teach the limitation wherein the locking complex increases the half-life of the double D-loop complex by a factor of at least 5-fold.

Applicant's arguments are not considered persuasive for the following reasons:

1. The rejection of the previous claims remains intact for the instantly rejected claims for the reasons set forth above in the reiteration/clarification of the rejection in regard to the instantly pending claims.
2. Applicant's assertion that Pati does not teach a limitation where the locking complex increases the half-life of the double D-loop complex by a factor of at least 5-fold is not persuasive because this limitation is a necessary feature of the teachings of Pati. Pati teaches a composition comprising a double D-loop comprising a target nucleic acid, and both a first and second single stranded nucleic acid with flanking regions that are capable

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of hybridizing to the target nucleic acid, where each single stranded nucleic acid has an internal homology clamp region capable of interacting (see for example Figure 13B and corresponding description). As per Applicant's own definition, an internal homology clamp is a simple anchoring/locking sequence (see for example page 21, lines 34-40 of the instant application). Therefore, Pati teaches all of the structural limitations of the claimed invention. Since the function of the invention is a direct result of the structure of the claimed invention, Pati *must necessarily* teach a half-life that is at least about 5-fold longer than a double D-loop lacking the internal homology clamp. There are no other structural limitations set forth in the instantly rejected claims, therefore this functional limitation can have no other basis than what is already taught by Pati.

In conclusion, Applicant's assertion that Pati does not teach all of the elements of the claimed invention is not persuasive. Pati must inherently teach the functional property (where the locking complex increases the half-life of the double D-loop complex by a factor of at least 5-fold) because all of the structural limitations of the claim are met by the teachings of Pati; therefore there is no reason to believe the functional limitations are not met. As a result, the rejection by Pati is not overcome by the amended claims.

Allowable Subject Matter

Claims 116-118 and 120 are allowed.

Claims 115, 138 and 141 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

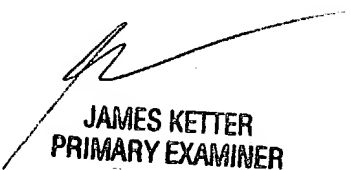
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson, Ph.D.
AU 1636



**JAMES KETTER
PRIMARY EXAMINER**